REMARKS

This is in response to the Office Action mailed February 28, 2006.

Claims 1, 2, 32, 33, 34 and 47 have been amended to further particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims do not include any amendments for a purpose of limiting the inventive subject matter, but rather are intended to emphasize certain aspects of the invention already set forth in the claims. Support for the amendments can be found throughout the originally filed application, e.g., see paragraphs 14 and 19 or original claim 1. No new matter has been added. Independent claim 1 and its dependent claims 2-46 and 49-52 and independent claim 47 are presented for consideration.

Election/Restriction

Applicants appreciate the Examiner's withdrawal of the restriction requirement from the previous office action.

Rejections under 35 U.S.C. § 112

The Examiner has rejected claim 2 under 35 U.S.C. §112, second paragraph, because claim 2 recites the limitation "the drug release layer" in line 2 and that there is insufficient antecedent basis for this limitation in the claim. Claims 2 and 32-34 have been amended to replace the term "the drug release layer" with "the drug reservoir layer" which should obviate the Examiner's rejection.

Rejections under 35 U.S.C. § 102

The Examiner has rejected claims 1-26, 28-35, 39, 47, and 49-52, under 35 U.S.C. §102(e) as being unpatentable over Pacetti (US 6,663,662).

The present invention as set forth in independent claim 1 is directed to a stent having a coating comprising: (a) a primer layer of two or more polymers, and (b) an outermost drug reservoir layer of two or more polymers comprising a drug stabilizing polymer, the primer layer polymers being distinct from the drug reservoir layer polymers, the drug reservoir layer further comprising one or more active agents.

In presenting such a distinct coating composition, the invention provides an outermost drug reservoir/release layer that protects and stabilizes the one or more active agents during sterilization and storage. The coating allows sufficient adhesion and flexibility to remain intact upon stent expansion and during a sustained period thereafter, and release of efficacious amounts of the active agent at the site of stent expansion.

The Examiner alleges, that in regard to claims 1-2, 47 and 49-52, Pacetti "discloses a primer layer/anchor polymer comprising one or more polymers (col. 4, line 38 to col. 8, line 42), a drug reservoir layer comprising an intermediate layer (34) and a drug release layer (28) that have one or more polymers and one or more active agent (col. 4, line 45 to col. 15, line 46)."

The present claims are not anticipated by Pacetti because the stent of Pacetti is both structurally and functionally different from the stent of the present system. First, the layer of Pacetti indicated by the Examiner as the "drug release layer (28)" is in fact an outer diffusion (barrier) layer (28), which controls drug release and does not contain an active agent, but is positioned over an optional drug reservoir layer (34). In contrast, the present invention comprises an outermost drug reservoir/release layer. Second, the optional drug reservoir layer and optional primer and/or adhesive layers of Pacetti preferably contain the same polymers. In contrast, the present invention

requires that the polymers in each layer be different than those polymers contained in the other layer.

Pacetti is primarily directed to a diffusion barrier or coating for an implantable medical device, such as a stent, for inhibiting or reducing the rate of release of an active ingredient carried by the device (e.g., abstract, field of the invention and claims). The diffusion barrier, which contains particles and can be made from a polymeric material, serves as an outer barrier layer for the prosthesis. The prosthesis can include cavities containing an active ingredient for the release of the active ingredient when the stent is implanted, or alternatively, the prosthesis can include an *inner* reservoir coating carrying an active ingredient (column 2, lines 46-55). The diffusion layer containing the particles acts as a rate reducing membrane for the release of the underlying active ingredient (column 2, lines 55-57).

The *outer* coating (e.g., the rate-reducing membrane or diffusion barrier as used throughout the description, column 13, line 27-column 15, line 46, the coating of claims 1 and 2, the first layer of claims 3 and 4, the second region of claim 27 or the barrier layer of claim 32) of the stent disclosed by Pacetti covers cavities containing the active ingredient (e.g., column 16, lines 5-11, and claim 2) or an *inner* drug containing coating (e.g., the active ingredient-containing or reservoir coating as used throughout the description, column 8, line 44-column 13, line 25, the second coating of claim 3, the third coating of claim 4, the first region of claim 27 or the first layer of claim 32). Pacetti also discusses an optional adhesive coating (e.g., the primer layer as used throughout description, column 4, line 35-column 8, line 42, the second coating of claim 4 or the third region of claim 28).

The stent of Pacetti is therefore structurally different from the present invention, which has an outermost drug reservoir/release layer. Moreover, the structural differences of Pacetti result in a functionally different device in that drug release from the inner drug reservoir layer is controlled by the outer diffusion layer. In contrast, the outermost drug reservoir/release layer of the present invention controls drug release.

Pacetti does not teach or disclose or suggest an *outermost* drug reservoir/release layer as in the present invention.

Moreover, independent claims 1 and 47 require a primer layer having polymers distinct from the polymers of the outermost drug reservoir layer. In contrast, Pacetti teaches that, if an optional primer layer or drug reservoir coating are used, then the choice of polymer for the reservoir coating or diffusion layer, respectively, can be the same in order to significantly reduce or eliminate any interfacial incompatibilities, such as lack of adhesive tie or bond, which may exist with the employment of two different polymeric layers (column 12, lines 55-63; column 13, lines 40-45 and Examples). Accordingly, Pacetti does not teach or disclose a coating with primer layer polymers being distinct from the drug reservoir layer polymers.

Therefore, claims 1 and 47 are not anticipated under 35 U.S.C §102 because Pacetti does not teach or disclose a stent having a coating comprising (a) a primer layer of two or more polymers, and (b) an outermost drug reservoir layer of two or more polymers comprising a drug stabilizing polymer, the primer layer polymers being distinct from the drug reservoir layer polymers, as set forth by the present invention.

The Examiner further contends that Pacetti teaches the additional elements of dependent claims 2-23, 25-26, 29-35, 39-42 and 49-52. Claims 2-23, 25-26, 29-35, 39-42 and 49-52 are

dependent from and therefore include all the limitations of claim 1. Therefore, dependent claims 2-23, 25-26, 29-35, 39-42 and 49-52 are not anticipated by Pacetti for the same reasons stated above.

Therefore, Pacetti does not anticipate independent claim 1 and its dependent claims 2-23, 25-26, 29-35, 39-42, and 49-52, and independent claim 47, and the rejection should be withdrawn.

Rejections under 35 U.S.C. § 103

The Examiner has rejected claims 27, 36-38, and 40-46, under 35 U.S.C. §103(a), as being unpatentable over Pacetti (US 6,663,662). The Examiner asserts that Pacetti discloses all the limitations of the claims except for the material as claimed, which are allegedly well known in the art at the time the invention was made to employ the materials as claimed into Pacetti's coating. The Examiner concludes that doing so would amount to mere substitution of one material for another within the same art that would perform equally well in Pacetti's coating or device without special functional significance are not patentable.

Claims 27, 36-38, and 40-46 are dependent from and therefore include all the limitations of claim 1. These claims, as discussed above for claim 1, are structurally and functionally different from Pacetti. Pacetti does not disclose, teach or suggest a stent having a coating comprising (a) a primer layer of two or more polymers, and (b) an *outermost* drug reservoir layer of two or more polymers comprising a drug stabilizing polymer, the primer layer polymers *being distinct* from the drug reservoir layer polymers, as set forth by the present invention. In fact, Pacetti teaches away from the present invention by requiring an outermost diffusion layer that covers an active ingredient or, optionally an inner drug reservoir layer.

The Examiner has provided no indication that these claim elements are disclosed or made obvious by Pacetti and has failed to present a *prima facie* case of obviousness. So the rejection should be withdrawn.

The Examiner further notes that the limitation "the primer layer polymers being distinct from the drug reservoir layer polymers" encompasses the same polymers being used for the primer layer and drug reservoir layer but two layers are distinct, one layer of polymer on top of the other layer of polymers.

Applicants disagree with the Examiner's characterization of the invention. The phrase "the primer layer polymers being distinct from the drug reservoir layer polymers" means that the polymers used in one layer, e.g., the primer layer, should be distinct from the polymers used in the other layer, e.g., the drug reservoir layer. Pacetti teaches away from the present invention by emphasizing the use of the same polymers in various layers, e.g., Examples 1-28.

Therefore, dependent claims 27, 36-38, and 40-46 are not obvious under 35 U.S.C. §103 over Pacetti and the rejection should be withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 1-47 and 49-52 and that the application be passed to issue. If the Examiner believes, for any reason, that personal

communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

Please charge any necessary fee or credit any overpayment in connection with this Information Disclosure Statement to Deposit Account No. 22-0261.

Respectfully submitted,

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